

Serial No. 09/259,758

REMARKS/ARGUMENTS

Claims 2-13, 18-30, 33-41, and 51-60 remain in this application. No claims have been canceled herein. No claims have been amended herein.

All the claims were rejected by the outstanding Office Action. The rejections will be addressed in the same order they appeared in the Office Action. Applicants note that many of the same rejections were addressed in earlier responses, all the earlier responses are incorporated herein by reference.

The Office Action rejected claims 7-10, 12, 18-30, 35-41, 51, and 55, 57-60 under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598). The Office Action states:

"With respect to claim 51, Clark et al teaches a process and an apparatus for sterilizing a medical device (col. 1, lines 7-20), which includes the following concepts: subjecting contact lens (col. 7, lines 1-3) to UV in the range of 240 to 280 NM (col. 3, lines 60-63), wherein the contact lens is in a hermitically sealed container (col. 8, line 33), and further the container is transmissive to at least 50% of UV (abstract, lines 3-5, col. 3, lines 53-54, lines 59-63. Thus, such citations include any percentage value for transmissivity. For example, 80% or 50% or the like) in substantially all directions (figure 1, 12) such that package 12 is made of material which will transmit in all directions and capable of holding contact lens (col. 6, lines 63-67 and col. 7, lines 1-3). In col. 7, lines 1-3, Clark states that contact lens packages can be used in the apparatus of figure 1. Then Clark goes on to further show that various materials can be used to design product packages including a contact lens, which can be used in the apparatus of figure 1 (col. 7, lines 3-12). As a result, various designs with various materials can be constructed to hold contact lenses according to Clark with or without a foil. Thus, it would have been obvious to one having ordinary skill in the art to modify Clark's contact lens package by designing a container without a foil since Clark discloses the use of various materials in designing such a package."

Applicants traverse this rejection. Although it is true that at col. 6, lines 63-67 and col. 7, lines 1-3, Clark states that a contact lens can be treated by the method shown in Figure 1, Clark does not teach nor suggest that the contact lens container can or should be transmissive to radiation in substantially all directions as Applicants have claimed in claim 51, and therefore all the dependent claims too.

Clark described a typical contact lens package consisting of a thermoplastic bowl and a foil backing on the bottom. (It is conventional in the contact lens packaging art to refer to this layer as the lidstock, because it is the layer that is peeled off the bowl to access the contact lens within the package.) The Office Action in the quoted language above states: "...package 12 is made of material which will transmit in all directions and capable of holding contact lens (col. 6, lines 63-67 and col. 7, lines 1-3)." That is not true. Package 12 is described as a "parental or

Serial No. 09/259,758

enteral package" (for example, see, col. 5, lines 45-46, and col. 6, lines 56-62). Col. 6, lines 63-67 and col. 7, lines 1-3 do not state that package 12 is capable of holding a contact lens as the Office Action states. Col. 6, lines 63-67 and col. 7, lines 1-3 state: "In this way, an effective method is provided for sterilizing not only parenteral or enteral packages, but product contents thereof, without requiring...autoclaving. In addition, other product containers and products contained therein may be treated using the approach of this embodiment. For example, contact lens packages and the contact lenses contained therein can be treated using the above-approach." (Emphasis added). That is not a teaching or suggestion to put a contact lens in a parenteral or enteral package. It is a teaching to put the contact lens package that is shown in Figures 3, 4, 5 and 6 into the apparatus shown in Figure 1, and the contact lens package that is shown in Figures 3, 4, 5, and 6 has a foil backing adhered to the bottom 60 of the polyolefin panel 54. The foil backing is not transmissive to uv radiation.

#12 ?
Further at col. 7, lines 1-3 the only suggestion Clark made was to modify the thermoplastic bowl material of the contact lens package. Clark did not suggest modifying the foil backing (lid). Clark states at col. 7, lines 1-3: "For example, contact lens packages and the contact lens contained therein can be treated using the above-approach. As a result, materials such as Olefins, nylon, and composite materials may advantageously be employed in product packages, instead of more conventional materials, such as polyvinyl chloride (PVC)." Clark does not state that olefins, nylon, and composite materials may advantageously be employed in product packages instead of foil backing layers. Modifying the blister material of the contact lens container disclosed by Clark as suggested by Clark, therefore, will not render the contact lens container transmissive to radiation in substantially all directions, as required by Applicants' claims. Therefore there is no teaching or suggestion in Clark to remove the foil from the contact lens package. There is no motivation provided by Clark either, because Clark indicates that the apparatus is effective at sterilizing the contact lens packages shown in Figures 3 and 5. (Col. 8, lines 53-57). Clark, therefore, does not teach nor suggest modifying the contact lens container that is disclosed by Clark to provide for transmission in substantially all directions. It is respectfully requested that the rejection of claims 7-10, 12, 18-30, 35-41, 51, and 55, 57-60 be withdrawn.

Further, in the "Response to Arguments", the Office Action states: "When the container [of Clark] is used in the apparatus of figure 1, the entire top surface and the sides of the container are exposed to radiation such that the container in substantially all directions is exposed to UV

Serial No. 09/259,758

light." The exposure of the container in substantially all directions is not a limitation in Applicants' invention, it is the transmissivity of the container in substantially all directions that is a limitation in Applicants' invention.

The Office rejected claims 7-10 for the following reason:

"With regard to claims 7-10, Clark discloses the following: more than 1 radiation source (col. 6, line 26), radiation sources pulse substantially simultaneously (col. 10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims), and flash lamps comprises a reflector and a lamp (figure 1, 22) wherein the fluence of each is at the focal plane of reflector (figure 1, 22:20)."

Applicants traverse this rejection. Col. 10, lines 35-37 do not mention radiation sources pulsing simultaneously. Clark discloses that 1-3 flashes are delivered in a short time, but does not state that any of those flashes involve lamps flashing simultaneously. The Examiner is obviously reading into the reference elements of the Applicants' invention. Further, claim 10 claims a specific minimum amount of UV radiation that must reach the focal plane, which is not taught or suggested by the large ranges of broad spectrum radiation that is disclosed by Clark. The term focal plane is not even mentioned in Clark. It is therefore respectfully requested that the rejection of claims 7-10 be withdrawn for the reasons just stated and the reasons discussed above.

The Office Action rejected claim 12, because, "Clark teaches that the radiation is delivered by flash lamps in at most three pulses (col. 9, lines 62-67 and col. 10, lines 33-37)."

Applicants traverse this rejection, Clark does not teach that each pulse includes flash lamps flashing simultaneously. Applicants' claim 12 is dependent on claim 8. Clark discloses 1-3 individual flashes, whereas Applicants claim that the radiation sources are pulsing simultaneously. Therefore, Applicants claim the delivery of at least twice the radiation disclosed in Clark, which is not taught nor suggested by Clark and is therefore patentable over Clark. It is respectfully requested that this rejection of claim 12 be withdrawn.

The Office Action rejected claims 18-30. The Office Action states:

"With regard to claims 18-30, Clark discloses the following: the contact lens blocks at least 50% of the UV radiation (col. 4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%) such that the range of UV radiation is in the range 240-280 NM (Col. 3, line 3), container comprises an aqueous solution (col. 8, line 4), subjecting a medical device (col. 1, lines 13-15) to UV radiation (col. 3, lines 60-62) in the range of 240-280 NM (col. 3, lines 60-63) using energy value at least 18 mj/cm² or 30 mj/cm² or 36 mj/cm² (col. 8, lines 10-12), various time ranges for applying the radiation such that all the values in the claims fall into (col. 8, lines

Serial No. 09/259,758

11-12), modifying radiation from a radiation source to eliminate wavelengths which would damage contact lens (col. 3, line 36, line 38, and col. 4, lines 55-57) such that contact lens are sterilized (col. 6, lines 63-65 and col. 7, lines 1-3), and container comprises a non-preserved aqueous solution (col. 1, lines 10-13)."

Applicants traverse these rejections for all the reasons above and for the following additional reasons: Col. 3, line 63 discloses a range of 180 to 300 nm radiation. That is the most narrow range of radiation disclosed by Clark. Applicants specify the energy requirements and transmissivity requirements are for a more narrow range (240-280 nm) of the radiation to achieve sterility of the product. Additionally, the total minimum energy densities that are taught by Clark are unclear, because the ranges of energy disclosed at col. 8, lines 10-15 are broad, and it is not clear if those amounts of energy are for the entire spectrum of radiation produced by the apparatus or for the specified ranges of radiation, and if it is for the entire spectrum, it does not state what portion of the entire spectrum is the radiation in the range of 240-280 nm.

Additionally, regarding the disclosure of a non-preserved aqueous solution. Clark at col. 8, line 3 states that the solution in the contact lens package disclosed therein is "a preservative fluid".

For these reasons, in addition with those disclosed above, claims 18-30 are allowable over Clark.

It is respectfully requested that the rejection of claims 18-30 be withdrawn.

The Office Action rejected claims 35-41. The Office Action states:

"With regard to claim 35-41, Clark teaches a process and an apparatus for sterilizing contact lens (col. 1, lines 7-1-20 and col. 4, lines 55-57) including the following: forming and placing a contact lens (col. 7, lines 61-67 and col. 8, lines 1-5) in a container, moving the container into an apparatus (col. 7, lines 1-3), which is light-tight (col. 8, lines 38-39) the use of packages or containers is disclosed made of thermoplastics (col. 3, line 48 and col. 1, lines 29-30); at least one flash lamp containing a rare gas as a luminous component (col. 10, lines 20-25), the contact lens blocks at least 50% of the UV radiation (col. 4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%), container comprises an aqueous solution (col. 8, line 4), and radiation sources pulse substantially simultaneously (col. 10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims)."

Applicants traverse these rejections for all the reasons above and for the additional reasons that follow. Regarding the disclosure of a light-tight apparatus, Applicants disagree that Clark teaches or suggests a light-tight apparatus. Col. 8, lines 38-40 of Clark states: "Referring to FIG. 4, a side view is shown of the contact lens package 50 of FIG. 3, being suitable for use in the sterilizing chamber (or tunnel) of the apparatus of FIG. 1." As shown in Figure 1, the sterilizing chamber or tunnel is open on its sides and front and back ends which will allow for light to exit the chamber or tunnel. Clark does not teach nor suggest a light-tight system;

Serial No. 09/259,758

therefore, Applicants' invention of claims 35-41 are not obvious for this reason, and all the reasons above too. The rejection based on the flash lamps pulsing substantially simultaneously was already addressed above. For these reasons and the reasons earlier discussed above, the rejections of claims 35-41 should be withdrawn.

The Office Action rejected claim 55, because the Office Action states that Clark discloses a light-tight apparatus. For the reasons already stated Clark does not disclose a light-tight apparatus; therefore it is respectfully requested that this rejection be withdrawn.

The Office Action rejected claims 57-60 for the following reasons:

"With respect to claims 57-60, Clark et al teaches the following: at least one reflector directs radiation from each radiation source to a treatment area (figure 1, 18:22); treatment area is located at the focal plane of reflector (figure 8, 18:22 and the unlabeled rays). In addition; Clark et al teaches of a capacitance and a potential (col. 10, lines 1-8), however; Clark et al does not provide specific values for capacitance and for potential. Since the claims are trying to exactly accomplish what Clark et al teaches then it is intrinsic in the apparatus of Clark et al to encompass the same values for capacitance and a potential. Furthermore, Clark et al discloses the use of reflectors with enhanced reflection (col. 6, lines 42-44); and the reflector minimizes the non-ultraviolet radiation reaching the medical device (col. 6, lines 45-48). In addition, see col. 8, lines 11-15 for various energy values."

Applicants traverse this rejection for all the reasons above and for the additional reason that the reason Clark does not teach nor suggest Applicants' capacitance range, and it is not intrinsic in the apparatus of Clark, because Clark is not trying to accomplish the same process. Clark does not provide a contact lens package that is transmissive in substantially all directions. Clark also does not provide for flash lamps flashing simultaneously. The other differences were discussed earlier. Therefore, Clark does not make Applicants' capacitance levels obvious. For this reason and the reasons above claims 57-60 are allowable.

The Office Action rejected claims 2-6, 11, and 52-54 under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) and further in view of Shalaby et al (U.S.P.N. 5,422,068). The Office Action states:

"With respect to claims 2-6 and 11, Clark teaches the following: a sterility assurance level of at 10^{-6} (abstract, line 21), all the energy values in the claims fall within the teaching of Clark et al energy value range (col. 8, lines 10-12), which contains a specific low range value and a specific high range value, the application of UV radiation to spores (col. 9, lines 50-53), the usage of at least one pulsed radiation source (col. 6, line 26 and col. 3, lines 51-56), various time ranges for applying the radiation which all the values in the claim fall into (col. 8, lines 12-19), and pulsed radiation source in at most three pulses (col. 9, lines 62-67 and col. 10, lines 33-37). However, with regard to claims 52-54, Clark fails to disclose D value for *Bacillus Stearothermophilus*, ATCC 7953 and how to determine such a value. However, with respect to claims 52-54, Matner teaches a method for determining the efficacy of a

Serial No. 09/259,758

sterilization cycle (col. 1, lines 708) wherein it is known to use *Bacillus Stearothermophilus*, ATCC 7935 to verify how efficient a sterilization cycle is (col. 2, lines 35-39). Matner fails to teach D values specific for *Bacillus Stearothermophilus*, ATCC 7953. With regard to claims 52-54, Shalaby teaches the concept of D-value and its importance to sterility assurance level is explained (col. 3, lines 28-65). Also the D-values of *Bacillus Stearothermophilus* are shown (columns 6-11). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values (col. 3, lines 46-57). It would have been obvious to one having ordinary skill in the art to modify Clark's process by applying UV radiation to *Bacillus Stearothermophilus* ATCC 7935 in order to determine the sterilizing efficacy since such organisms are recognized as the most resistant form of microbial life (Matner, col. 5, lines 53-60 and col. 6, lines 3-4)."

Applicants traverse this rejection. The concept of a D-value was known, but the D-values for Applicants' process were not disclosed, taught, nor suggested, nor is it disclosed that *Bacillus Stearothermophilus* would be the most difficult microorganism to kill in Applicants' process.

Prior to Applicants' disclosure, it was believed and disclosed that *Aspergillus* spores were the most resistive to the effects of uv radiation. See Gritz et al, "Ultraviolet Radiation for the Sterilization of Contact Lenses", the CLAO journal, Oct. 1990, vol. 16, number 4, or Nirankari, "Sterilizing Contacts with Ultraviolet Light", Research to Prevent Blindness Science Writers Seminar. (These references were cited to the USPTO by Applicants in an IDS mailed on October 3, 2000). However, Applicants discovered that *Bacillus stearothermophilus* (ATCC 7953) was the hardest to kill, and the one for which a Dvalue should be determined to provide the required sterility assurance level for this method of sterilization. That was not taught nor suggested by the closest prior art, and was actually unexpected based on the prior art teachings and the characteristics of *Aspergillus niger* that were thought to protect it against the effects of uv radiation. Clark is cited as the closest prior art and it does not even mention *Bacillus stearothermophilus* in its examples. The references that the Examiner assembled indicate that a hindsight reconstruction occurred. The references do not even disclose uv radiation sterilization. For this reason and the reasons above, it is therefore respectfully requested that this rejection be withdrawn and claims 2-6, 11, and 52-54 be allowed.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Dunn et al (U.S.P.N. 4,910,942). The Office Action states:

"With regard to claim 12, Clark fails to disclose the use of laser. However, Dunn teaches of a method for sterilizing packaging of medical devices (col. 1, lines 17-21) wherein the usage of laser radiation is known (col. 2, lines 17-22). It would have been obvious to one having ordinary skill in the art

Serial No. 09/259,758

to modify Clark's process to include a laser source in order to sterilize light-transmissive containers (Dunn, col. 2, lines 14-15 and lines 18-19)."

Applicants traverse this rejection. Dunn does not teach a method of sterilizing packaging for medical devices (col. 1, lines 17-21) using laser radiation. Col. 2, lines 17-22 addresses sterilizing food and containers for food products, as does the rest of Dunn.

Applicants' claim a method of sterilizing a contact lens container and its contents. The combination of Dunn and Clark appears to be a hindsight reconstruction of the art, since there is no teaching or suggestion to use lasers to sterilize contact lens containers as Applicants have claimed. For this reason, and the reasons above, claim 12 is allowable. It is therefore respectfully requested that this rejection be withdrawn, and claim 12 be allowed to issue.

Claims 33-34 and 56 were rejected by the Office Action under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Heyl et al (U.S.P.N. 5,431,879).

The Office Action states:

"With respect to claim 33, Clark's container (12) consists essentially of thermoplastics (col. 7, lines 19-21 and col. 7, lines 3-6). However, Clark fails to disclose a container with a lid and a bowl. With respect to claim 33, Heyl's container includes a lid and a bowl (col. 9, lines 35-37). It would have been obvious to one having ordinary skill in the art to modify Clark's process to include a container made up of a lid and a bowl."

Clark discloses a contact lens container having a lid and a bowl. The bowl is equivalent to the blister and Clark's bottom 60 having the foil backing 58 is the lid of the container. Clark discloses a typical single-use contact lens package. The contact lens package is opened by peeling the bottom 60 away from the blister. However, Clark does not disclose, nor teach nor suggest a contact lens container that provides transmissivity in substantially all directions, as required by Applicants' claims. Therefore, for this reason, in addition to those described above, claim 33 is patentable over Clark and Heyl. It is respectfully requested that claim 33 be allowed.

The Office Action rejected claims 34 and 56. The Office Action states:

"With respect to claims 34 and 56, Clark discloses at least one flash lamp containing a rare gas as a luminous component (col. 10, lines 20-25), and the apparatus is light tight (col. 8, lines 38-39)."

Applicants agree that Clark discloses that the lamp contains a rare gas as the luminous component; however, claim 34 is allowable for all the reasons above. Applicants disagree that Clark teaches or suggests a light-tight apparatus. Col. 8, lines 38-40 of Clark states: "Referring

Serial No. 09/259,758

to FIG. 4, a side view is shown of the contact lens package 50 of FIG. 3, being suitable for use in the sterilizing chamber (or tunnel) of the apparatus of FIG. 1." As shown in Figure 1, the sterilizing chamber or tunnel is open on its sides and front and back ends which will allow for light to exit the chamber or tunnel. Clark does not teach nor suggest a light-tight system; therefore, Applicants' invention of claim 56 is not obvious for this reason and all the reasons above too.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If there are any remaining issues that prevent the immediate allowance of this application, kindly contact the Attorney for Applicants below to resolve them via an interview.

Respectfully submitted,

By: 

Anne B. Kiernan
Reg. No. 36,566

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2724
Dated: March 6, 2003